RECEIVED AT DRUG SAFETY SURVEILLANCE
27-FEB-1998-0455

McN

McNEIL CONSUMER I
FORT WASHING

Page ____

Individual Safety Report
3037711-9-00

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case #16 In confidence	51 yrs or ____ Date of birth:	(X)female ( )male	143 lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death 12/14/94 (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event	4. Date of this report
11/27/94 (mo/day/yr)	02/11/98 (mo/day/yr)

5. Describe event or problem

Reports of 19 cases compiled by attorney & sent to FDA;Agency forwarded these reports to McNeil upon request to Docket No.77N-094W,Ref.94,Vol.6 of 7. Of the 19 cases,11 were previously submitted to FDA by McNeil (Mfr.# 0158783A, 0171537A, 0284020A, 0325998A, 0374114A, 0495613A, 0505064A, 0505223A, 0505252A, 0599479A,0673820A). Case document #16 Death Summary indicates a 51yo F seen in ER(11/24/94) for mult.rib Fx; she began taking TYLENOL & LORCET, 1-2 tablets q3h for pain & continuing to consume large amts of alcohol. On 11/27/97. pt seen in ER for NAUSEA,admitted & then transferred to 2nd hosp for HEPATIC FAILURE & (METRORRHAGIA) vaginal bleeding that spontaneously stopped. Pt's ILEUS improved for a while, developed progressive respiratory difficulty & shocked lung (RESPIRATORY DISORDER),intubated & placed on respirator. Pt became comatose(COMA),ceased responding. Respirator was tapered off &pt expired (DEATH)12/14/94. Final Dx:Acute hepatic failure,secondary to combination of alcohol & acetaminophen, alcoholism, ileus,shock lung,HYPOKALEMIA & vaginal bleeding.

6. Relevant tests/laboratory data, including dates

11/27/94 SGOT=13000, Bili=27, ultrasound showed no ascites 12/5/94 PT=13.7, PTT=27.1, WBC=21600, Hgb=11.5, Hct=33.6, Na=119, K= 4.2, NH3=46 12/6/94 SGPT=368, SGOT=75, Bili=23.7, AlkPhos=327, LDH=205 12/8/94 Hgb=9.1,Hct=26.9 (See Sect.B.7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

significant for basically her heavy alcohol ingestion in the past; recent multiple rib fractures from her fall on 11/24/94; EXP LAP & bil. tubal ligation; allergic to sulfa & penicillin; (Cont'Sect.B.6) 12/9/94 K=3.3, PLT=182K 12/10/94 urine & sputum culture=E.coli, CXR= showed diffused bil. infiltrates, c/w pneumonia, cardiac failure or shock lung

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown TYLENOL product
#2 LORICET®

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1-2 tablets, q3hrs, po	#1 11/24/94-11/27/94; 4 days
#2 1-2 tablets, q3hrs, po	#2 11/24/94-11/27/94; 4 days

4. Diagnosis for use (indication)

#1 multiple rib fractures pain
#2 multiple rib fractures pain

5. Event abated after use stopped or dose reduced

#1 ( ) Yes (X) No ( ) N/A
#2 ( ) Yes (X) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 n/a	#2 n/a

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

OGEN®

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

FEB 27 1998

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- (x) other: attorney

4. Date received by manufacturer (mo/day/yr): 12/31/97

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH
RESPIRATORY DIS
ILEUS
HYPOKALEMIA
LIVER FAILURE
METRORRHAGIA
COMA

9. Mfr. report number: 0932142A

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	(X) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event